

"Does this mean that I have to fill out an NCR?"

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Non-conformance reports (NCRs) can be a sore spot for any analyst! Deciding when, how, and why to fill one out, who fills it out and what to do next is often a challenge. The first step is to define 'conformance'. In this context conformance may be defined as something that falls within defined, pre-set, acceptable parameters. A non-conformance is any unintentional departure from these set parameters. A non-conformance may involve data, equipment, supplies, services, procedures, or other factors. However, not all deviations from the 'norm' require the issuance of a non-conformance report. Responses to uncommon situations can range from initiating an NCR and corrective action plan for every incidence of non-conformance, to fixing the situation on the spot without an NCR and minimal documentation. For example: Some groups initiate an NCR whenever a monitored parameter (whether crucial or not) does not fall within acceptable limits, even if it has no impact on the final results. Other groups will only initiate an NCR when Quality Control results fall outside of acceptable limits and the deviation has the potential to affect sample or personnel results. The question is: When is it really necessary to initiate an NCR? Who decides (and encourages the analysts to fill out the NCRs) and what actions are mandatory after an NCR is initiated? This presentation presents ideas, methods, and examples on how to view and deal with non-conformance. Several ideas will be proposed that will help with the establishment of reasonable monitoring parameters, issuing of corrective actions, establishing an initiator for these actions, and final closure on NCR's and the corrective actions.

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